



NDA 20-622/S-015

TEVA Pharmaceuticals USA  
Attention: Dr. J. Michael Nicholas  
Senior Director, Regulatory Affairs  
1090 Horsham Road  
North Wales, PA 19454

Dear Dr. Nicholas:

Please refer to your supplemental new drug application dated March 16, 2001, received March 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Copaxone (glatiramer acetate) for Injection 20mg/vial.

We acknowledge receipt of your submission dated March 16, 2001. Your submission of March 16, 2001 constituted a complete response to our January 19, 2001 action letter.

This supplemental new drug application proposes numerous changes to the Copaxone Injection product labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the labeling text agreed to in our facsimile of June 29, 2001. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling faxed on June 29, 2001 and which is appended to this letter. These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-622/S-015/S-015." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

*{See appended electronic signature page}*

Russell Katz, M.D.  
Director  
Division of Neuropharmacological Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure: